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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/556,701	04/24/2000	Hitoo Nishino	0010-1106-0	7992

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/556,701

Applicant(s)

Nishino

Examiner

Gollamudi Kishore

Art Unit

1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 21, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 8, 12, 16, and 17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 8, 12, 16, and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: :1615

DETAILED ACTION

The request for the extension of time, the amendment and the terminal disclaimer filed on 8-21-02 are acknowledged.

Claims included in the prosecution are 1-3, 7-8, 12 and 16-17. The added claims 15 and 16 have been renumbered as 16 and 17 in accordance with rule 126.

Claim Rejections - 35 USC § 102

- 1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

- 2. Claims 1-3, 7-8, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/20555 of record.**

WO discloses a method of treatment or prevention of ischemic brain injury by administering melatonin (note the abstract, page 8, lines 10-30, page 9, lines 22-34, page 11, lines 14-16, Examples and claims). Since ischemia is the causative factor of brain edema, the prevention and the treatment thus, are implicit in WO's teachings. It is noted that

Art Unit: :1615

claims 8 and 12 recite food. Since the claims do not recite the specific foods and the mode of administration of food, the reference which recites compositions containing dextran (a sugar and therefore a food) given intravenously (hospital patients are given dextran routinely as a nourishment) meets the requirements of instant claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that the subject has an ischemic brain injury does not mean that the subject has brain edema. This might be true; however, if a person has ischemia caused brain edema, then by treating the ischemia, one is treating the edema also and instant claims do not exclude the condition. Applicant on page 2 of Instant specification states that brain edema cause by brain ischemia or deficient cerebral blood flow is called ischemic brain edema. The examiner cites US 5,137,871 which teaches that vasogenic edema of the brain which is produced by various adverse medical conditions, such as brain ischemia (lack of oxygen). According to this reference, brain blood vessels become more permeable when they are injured by lack of oxygen (note col. 3, lines 15-65). Therefore, the treatment of edema caused by ischemia which is due to lack of oxygen and the subsequent leakage of the blood contents is implicit in WO used in the rejection since stopping the leakage due to ischemia will treat the edema caused by ischemia. The examiner also cites US 5,520,912 which shows the relationship between ischemia and edema (see col. 3, line 6 through col. 4, line 67). The rejection is maintained.

Art Unit: :1615

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3, 7-8, 12 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO cited above.

As discussed above, WO discloses a method of treatment or prevention of ischemic brain injury by administering melatonin (note the abstract, page 8, lines 10-30, page 9, lines 22-34, page 11, lines 14-16, Examples and claims). Since ischemia is the causative factor of brain edema, it would have been obvious to one of ordinary skill in the art that a composition which is able to prevent ischemia would be preventing the edema also.

Although WO does not specifically state the composition is a food composition, it teaches the administration of the composition orally using additives and therefore, addition to food for oral consumption is deemed to be within the skill of the art.

Applicant provides no separate arguments for this rejection. The same response by the examiner as noted above are applicable here. The rejection is maintained.

5. Claims 8, 12, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/20555, further in view of Wurtman (4,687,763).

Art Unit: :1615

The teachings of WO have been discussed above. Although WO teaches the administration of melatonin orally, it does not specifically teach that the oral composition be a food composition. It is deemed obvious to one of ordinary skill in the art to administer food composition containing melatonin in the oral mode of administration taught by WO with a reasonable expectation of success, since the reference of Wurtman shows that melatonin is routinely administered as a component of food including a drink, a beverage, a wafer or candy (note the abstract and col. 2, lines 19-59).

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: :1615

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Art Unit: :1615

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

November 15, 2002